

REMARKS

Applicants respectfully request entry of amendments to claims 1-4, 6-10, and 12-14, and new claim 40. Please cancel claims 5 and 11, and withdraw claims 15-39, without prejudice or disclaimer. Support for the amendments can be found throughout the specification, including paragraphs [0006], [0014], [0043], [0045], Table 3, the Sequence Listing, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 1-4, 6-10, 12-14, and 40 are in condition for allowance, and respectfully request that the claims as amended be entered.

Restriction Requirement

Applicants wish to thank the Examiner for rejoining the primer pairs and acknowledging Applicants' request for rejoinder of process claims with an allowable product as required by M.P.E.P. §806.05(h).

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 3-7 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. As claim 5 has been canceled, the rejection as applied to this claim is rendered moot.

Applicants have amended the claims, where appropriate, to recite "nucleic acid sequence." The term "sequence," which is what a sequence identifier denotes, is a term of art and would be known to one of skill in the biotechnology art, to which this invention belongs. As such, one of skill in the art would understand the metes and bounds of the claims.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Bohne et al., Blais et al., or Camilli et al.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited references teach the elements as recited in the present claims, specifically, that the references teach virulence genes “*prfA*, *pclA*, *hyl*[sic], *mpl*, *plcB*, and *actA*.” The instant claims have been amended to recite a specific sequence identifier: i.e., SEQ ID NO: 9. Review of SEQ ID NO: 9 demonstrates that a contiguous reading frame is present within residues 887 to 1500, which delimit a target for PCR amplification using primers defined by SEQ ID NO:26 and SEQ ID NO:27. As a point of reference, the predicted amino acid sequence for this contiguous reading frame is given below:

“VTPLTQLTYFDCSVNPLTELDVSTLSKLTLHCIQTDLLEIDLTHNTQLIYFQAEGCRKI
KELDVTHNTQLYLLDCQAAGITELDLSQNPKLVYLYLNNTTELDELDVSHNTKLKSLSCVN
AHIQDFSSVGKIPALNNNFEAEGQTITMPKETLTNNSLTIAVSPDLDQFGNPMNIEPGD
GGVYDQATNTITWENLSTDNPBV”

Review of the amino acid sequences available from the National Center for Biotechnology Information (NCBI) for the sequences recited in the Action (see, e.g., Exhibits A-F), show that no significant homology exists between the virulence genes recited in the Action and the predicted amino acid sequence from the contiguous reading frame present within SEQ ID NO: 9. Because the present claims expressly recite a sequence identifier, which is not taught or suggested in the references cited, neither Bohne et al., Blais et al., nor Camilli et al., separately or in combination, anticipate the claimed invention.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

Therefore, because the instant claims recite a sequence identifier which is not taught or suggested in the references cited, the cited references, alone or in combination, do not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Claims 1-14 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Kunst et al. or Glasner et al. As Claims 5 and 12 have been canceled, the rejection as applied to these claims is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited references teaches the elements as recited in the present claims. Glasner et al. is offered to demonstrate the isolation of virulence genes “*prfA*, *pclA*, *hyl*[sic], *mpl*, *plcB*, and *actA*.” Again, as stated above, the instant claims have been amended to recite a specific sequence identifier: i.e., SEQ ID NO: 9. Review of SEQ ID NO:9 demonstrates that a contiguous reading frame is present within residues 887 to 1500, which delimit a target for PCR amplification using primers defined by SEQ ID NO:26 and SEQ ID NO:27. As a point of reference, the predicted amino acid sequence for this contiguous reading frame is given below:

“VTPLTQLTYFDCSVNPLTELDVSTLSKLTLHCIQTDLLEIDLTHNTQLIYFQAEGCRKI
KELDVTHNTQLYLLDCQAAGITELDLSQNPKLVYLYLNNTTELVDVSHNTKLKSLSCVN

AHQDFSSVGKIPALNNNFEAEGQTITMPKETLTNNSLTIAVSPDLDQFGNPMNIEPGD
GGVYDQATNTITWENLSTDNPBV”

Review of the amino acid sequences available from NCBI for the sequences recited in the Action (see, e.g., Exhibits A-F), show that no significant homology exists between the virulence genes recited in the Action and the predicted amino acid sequence from the contiguous reading frame present within SEQ ID NO: 9. Because the present claims expressly recite the sequence identifier, which is not taught or suggested in Glaser et al., the reference does not anticipate the claimed invention.

Regarding Kunst et al., the Office Action states that the claimed sequences, SEQ ID NO: 9, 26, and 27, are disclosed in the reference. While it is not clear as to which search report the Action is referring to in support of the statement that the sequence identifiers are disclosed, the Kunst et al. sequences can be obtained from the PTO website at, for example:

<http://seqdata.uspto.gov/?pageRequest=viewSequecne&DocID=20040018514&seqID=2870>
and

<http://seqdata.uspto.gov/?pageRequest=viewSequence&DocID=US20040018514A1&seqID=2909>.

Applicants submit that review of SEQ ID NO: 2909 and 2870 demonstrates that these sequences do not anticipate SEQ ID NO: 9, 26, or 27 as claimed.

Exhibits G and H represent the nucleic acid sequences denoted by sequence identifiers 2870 and 2909 of Kunst et al. At minimum, because both SEQ ID NO: 2870 and 2909 have fewer nucleotides than SEQ ID NO: 9 (2556/759 vs. 2640), SEQ ID NO: 2870 and 2909 are not identical to SEQ ID NO: 9, and thus, do not anticipate SEQ ID NO: 9 as claimed.

Further, Applicants submit that there is no teaching in Kunst et al. which would lead one of skill in the art to make the primers as recited. In the same fashion that genomes do not

inherently anticipate isolated structural genes for want of enablement, Kunst et al. do not provide sufficient guidance to specifically identify the primer sequences as claimed (see, e.g., Chester v. Miller, 15 U.S.P.Q.2d 1281 (Fed. Cir. 1990), where the court stated that “[t]o be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure.”). Both SEQ ID NOS: 2870 (2556 nt) and 2909 (759 nt) are orders of magnitude longer than either SEQ ID NO: 26 (21 nt) or 27 (20 nt). And while Kunst et al. may or may not suggest the use of primers for the detection of *Listeria* contamination, there is no guidance which would direct the skilled artisan to choose the specific primers as claimed among all the possible alternative fragments that comprise SEQ ID NOS: 2870 and/or 2909.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

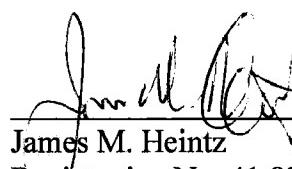
Therefore, because the instant claims a) recite a sequence identifier which is not taught or suggested in the cited references and b) recite specific primer sequences which would not be enabled by the teachings of the cited references, neither Glasner et al. nor Kunst et al. anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants counsel, James M. Heintz at 202.861.4167.

Respectfully submitted,

DLA PIPER US LLP



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Facsimile No. 202.223.2085

EXHIBIT A

Entrez Protein

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PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Books

Search Protein for

Limits Preview/Index History Clipboard Details

Display GenPept Show 5 Send to

Range: from begin to end Features: CDD

1: CAA43524. Reports prfA [Listeria mo...[gi:48960]

BLink, Conserved Domains, Links

Comment Features Sequence

LOCUS CAA43524 237 aa linear BCT 12-JUN-2006
 DEFINITION prfA [Listeria monocytogenes].
 ACCESSION CAA43524
 VERSION CAA43524.1 GI:48960
 DBSOURCE embl accession X61210.1
 KEYWORDS
 SOURCE Listeria monocytogenes
 ORGANISM Listeria monocytogenes
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
 REFERENCE 1
 AUTHORS Mengaud,J., Dramsi,S., Gouin,E., Vazquez-Boland,J.A., Milon,G. and Cossart,P.
 TITLE Pleiotropic control of Listeria monocytogenes virulence factors by a gene that is autoregulated
 JOURNAL Mol. Microbiol. 5 (9), 2273-2283 (1991)
 PUBMED 1662763
 REFERENCE 2 (residues 1 to 237)
 AUTHORS Dramsi,S., Kocks,C., Forestier,C. and Cossart,P.
 TITLE Internalin-mediated invasion of epithelial cells by Listeria monocytogenes is regulated by the bacterial growth state, temperature and the pleiotropic activator prfA
 JOURNAL Mol. Microbiol. 9 (5), 931-941 (1993)
 PUBMED 7934921
 REFERENCE 3 (residues 1 to 237)
 AUTHORS Cossart,P.F.
 TITLE Direct Submission
 JOURNAL Submitted (09-AUG-1991) P.F. Cossart, Inst Pasteur, Lab de Gen Mol des Listeria, 28 rue du DR. Roux, 75015 Paris, FRANCE
 COMMENT See M55160 for overlapping sequence.
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 /strain="LO28"
 /db_xref="taxon:1639"
Protein 1..237
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Region 18..210
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 /db_xref="CDD:31008"

CDS 1..237
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/db_xref="InterPro:IPR000595"
/db_xref="InterPro:IPR001808"
/db_xref="InterPro:IPR011991"
/db_xref="InterPro:IPR012318"
/db_xref="PDB:1OMI"
/db_xref="PDB:2BEO"
/db_xref="PDB:2BGC"
/db_xref="UniProtKB/Swiss-Prot:P22262"

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121 qkqvsyslak fndfsingkl gsicgqlil tyvygketpd gikitldnlt mqelgyssgi
181 ahssavsrii sklkqekviv yknscfyvqn ldylkryapk ldewfylacp atwgkln
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Jan 29 2007 13:59 11

EXHIBIT B

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PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Books

Search Protein for

Limits Preview/Index History Clipboard Details

Display GenPept Show 5 Send to

Range: from begin to end Features: CDD

1: AAY54619. Reports PlcA [Listeria mo...[gi:66737346]

BLink, Conserved Domains, Links

Features Sequence

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 ACCESSION AAY54619
 VERSION AAY54619.1 GI:66737346
 DBSOURCE accession DQ054593.1
 KEYWORDS
 SOURCE Listeria monocytogenes
 ORGANISM Listeria monocytogenes
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
 REFERENCE 1 (residues 1 to 269)
 AUTHORS Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.
 TITLE Virulence phenotyping and molecular characterization of a low-pathogenicity isolate of Listeria monocytogenes from cow's milk
 JOURNAL Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)
 PUBMED 16604266
 REFERENCE 2 (residues 1 to 269)
 AUTHORS Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.
 TITLE Direct Submission
 JOURNAL Submitted (07-MAY-2005) Institute of Preventive Veterinary Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou, Zhejiang 310029, China
 COMMENT Method: conceptual translation.
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 /strain="10403S"
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Protein 1..269
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121 kdyfyttprt dtsnkiptlk dvrkgill1s enhtkkplvi nsrkfgmqfg apnqviqddy
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241 ekvrglgili mdfpekqtik niiknnkfn

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EXHIBIT C

NCBI Protein [Sign In] [Regis]

PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Books

Search Protein for Go Clear

Limits Preview/Index History Clipboard Details

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BLink, Conserved Domains, Links

Features Sequence

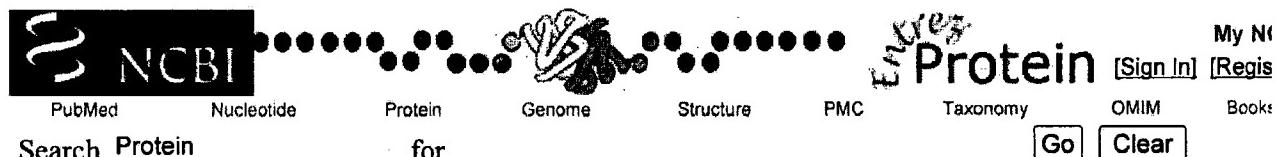
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 DEFINITION Mpl [Listeria monocytogenes].
 ACCESSION AAY54621
 VERSION AAY54621.1 GI:66737350
 DBSOURCE accession DQ054595.1
 KEYWORDS
 SOURCE Listeria monocytogenes
 ORGANISM Listeria monocytogenes
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
 REFERENCE 1 (residues 1 to 510)
 AUTHORS Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.
 TITLE Virulence phenotyping and molecular characterization of a low-pathogenicity isolate of Listeria monocytogenes from cow's milk
 JOURNAL Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)
 PUBMED 16604266
 REFERENCE 2 (residues 1 to 510)
 AUTHORS Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.
 TITLE Direct Submission
 JOURNAL Submitted (07-MAY-2005) Institute of Preventive Veterinary Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou, Zhejiang 310029, China
 COMMENT Method: conceptual translation.
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pfam02868"
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181 ivqvdaetga ilkkqnmlse veradthkdf qalgkganrl lqrplhvmki ndlfylvdrt
241 hkglirtfdl khntdtsgk vvsnktnmft dpefssavda hfyasevyey yknvhqlesl
301 dgkggeidsf vhyglncnna fwdgqeilyg dgdkknfkpf scaktivghe lthavigsa
361 gleyeqqsga lnesfadvgf yfiapnhwli gedvcvrgsr dgrirsikdp dkynqaahmk
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481 kkalqqaakd lygedaskkv aeaweavgvn
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EXHIBIT D



1: AAY54609, Reports PlcB [Listeria mo...[gi:66737326]

BLink, Conserved Domains, Links

Features Sequence

LOCUS AAY54609 289 aa linear BCT 21-AUG-2006
 DEFINITION PlcB [Listeria monocytogenes].
 ACCESSION AAY54609
 VERSION AAY54609.1 GI:66737326
 DBSOURCE accession DQ054583.1
 KEYWORDS .
 SOURCE Listeria monocytogenes
 ORGANISM Listeria monocytogenes
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
 REFERENCE 1 (residues 1 to 289)
 AUTHORS Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.
 TITLE Virulence phenotyping and molecular characterization of a low-pathogenicity isolate of Listeria monocytogenes from cow's milk
 JOURNAL Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)
 PUBMED 16604266
 REFERENCE 2 (residues 1 to 289)
 AUTHORS Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.
 TITLE Direct Submission
 JOURNAL Submitted (07-MAY-2005) Institute of Preventive Veterinary Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou, Zhejiang 310029, China
 COMMENT Method: conceptual translation.
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 /note="Zinc dependent phospholipase C; pfam00882"
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 CDS 1..289
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// 241 ivnaktkksy lvgnsewkkd tveptgarlr dsqqtlagfl efwskktne

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EXHIBITE E

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181 vadasesld ssmqsadest pqplkanqkp ffpkvvfkik dagkwvrdki denpevkai
241 vdksaglidq lltkkkseev nasdfpppdeelrlalpe tpmllgfnap tpsepssfef
301 pppptedele imretapsld ssftsgdlas lrsainrhse nfssdfppipt eeelngrggr
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481 tkpqetvlre nktpfiekqa etnkqsinmp slpvigkeat esdkeemkpg teekmveese
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601 rknn
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EXHIBIT F

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PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Books

Search Protein for

Limits Preview/Index History Clipboard Details

Display GenPept Show 5 Send to

Range: from begin to end Features: CDD

1: ABH11412. Reports HlyA [Listeria mo...[gi:115395038]

BLink, Conserved Domains, Links

Features Sequence

LOCUS ABH11412 277 aa linear BCT 27-DEC-2006
 DEFINITION HlyA [Listeria monocytogenes].
 ACCESSION ABH11412
 VERSION ABH11412.1 GI:115395038
 DBSOURCE accession DQ812517.1
 KEYWORDS .
 SOURCE Listeria monocytogenes
 ORGANISM Listeria monocytogenes
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
 REFERENCE 1 (residues 1 to 277)
 AUTHORS Ducey,T.F., Page,B., Usgaard,T., Borucki,M.K., Pupedis,K. and Ward,T.J.
 TITLE A Single-Nucleotide-Polymorphism-Based Multilocus Genotyping Assay for Subtyping Lineage I Isolates of Listeria monocytogenes
 JOURNAL Appl. Environ. Microbiol. 73 (1), 133-147 (2007)
 PUBMED 17085705
 REFERENCE 2 (residues 1 to 277)
 AUTHORS Ducey,T.F., Page,B., Usgaard,T., Borucki,M.K., Pupedis,K. and Ward,T.J.
 TITLE Direct Submission
 JOURNAL Submitted (22-JUN-2006) Microbial Genomics and Bioprocessing Research Unit, United States Department of Agriculture, Agricultural Research Service, 1815 N. University Street, Peoria, IL 61604, USA
 COMMENT Method: conceptual translation.
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Region <1..277
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CDS 1..277
 /gene="hlyA"
 /coded_by="DQ812517.1:<1..>831"
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61 lqalgvnaen ppayissvay grqvylklst nshstkvkaa fdaavsgksv sgdveltnii
121 knssfakaviy ggsakdevqi idgnlgdlrd ilkkgatfnr etpgvpiayt tnflkdnela
181 viknnseyie ttskaytdgk inidhsggvv aqfniswdei nydpegneiv qhknwseennk
241 sklahftssi ylpgnarnin vyakectgla wewwrtv

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EXHIBIT G



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Publication Site for Issued and Published Sequences (PSIPS)

PSIPS View Sequence(s): 2870 for 20040018514

Here is the list of the requested sequences.

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No: <211> LENGTH: 2556
 <212> TYPE: DNA
 <213> ORGANISM: List
 <400> SEQUENCE: 2870

 First Sequence
 Next Sequence
 Previous Sequence
 Last Sequence

 Full Text Publication

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[Page](#)
[NCBI Home](#)
[PIW and AIW](#)
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Help Page
FAQ

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Last Modified: 02/05/2007 09:30:31

EXHIBIT H



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Sequence ID
No:

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Previous Sequence	
Last Sequence	
Full Text Publication	
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[FAQ](#)

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[NCBI Home](#)

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